MAR 27 2000

K000021



## VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990, and Title 21 of the Code of Federal Regulations (21 CFR) Part 807, and in particular §807.92, the following summary information is provided:

### A. Submitted by:

Steve Reitzler, RAC
Authorized Regulatory Agent for AESCULAP®
13221 Maricotte Place
San Diego, California 92130
Telephone: (619) 977-1465
Date Prepared: December 28, 1999

### B. Device Name

Trade or Proprietary Name: AESCULAP® *Bone Wax*

Common or Usual Name: Bone Wax

Classification Name: [*Device Unclassified*]

### C. Predicate Devices

The subject device is substantially equivalent to other bone waxes distributed commercially in the U.S., including Ethicon Bone Wax (Preamendment, Ethicon, Inc.), Lukens Bone Wax (K791495, Lukens Medical Corporation), and Auto Suture® Bone Wax (K971680, U. S. Surgical Corporation).

### D. Device Description

AESCULAP® *Bone Wax* is a sterile, ivory-white, plastic, kneadable ceraceous material intended to aid mechanically in the control of bleeding of bone injuries, whether attributable to trauma or to surgical intervention. It is composed principally of refined beeswax with a softening agent added, and is supplied sterile in thin sheets.

### E. Intended Use

AESCULAP® *Bone Wax* is intended to aid in the control of bleeding in bone injuries.

## F. Comparison to Predicate Devices

As was established in this submission, the subject device is substantially equivalent to the predicate devices identified above, in that the device has the same intended use, is composed of refined beeswax mixed with a softening agent, is biocompatible, and is supplied sterile in a soft, kneadable form for ease of application to bone surfaces.

## G. Summary of Non-Clinical Tests

A series of *in vitro* and *in vivo* tests have established that the subject device is biocompatible, in accordance with the recommendations of ISO 10993-1.

## H. Summary of Clinical Tests

(Not applicable.)

## I. Conclusions of Non-Clinical and Clinical Tests

The device is reasonably safe for use as an implantable mechanical aid to control hemorrhage of bone surfaces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

AESCULAP, Inc.
c/o Mr. Steve Reitzler, RAC
Regulatory Consulting Service
13221 Maricotte Place
San Diego, California 92130

Re: K000021
Trade Name: Bone Wax
Regulatory Class: Unclassified
Product Code: MTJ
Dated: December 30, 1999
Received: January 4, 2000

Dear Mr. Reitzler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## V. Draft Labeling

### A. Indications for Use

510(k) Number (if known): K000021

Device Name: AESCULAP® *Bone Wax*

Indications for Use:

AESCULAP® *Bone Wax* is intended to aid in control of bleeding in bone injuries.

NRO for cmw

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000021

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)